REMARKS

The present Office Action addresses and rejects claims 1, 3, 4, 8-15, 17-24, 26-30, and 32-33. Applicants respectfully request reconsideration in view of the amendments and remarks herein.

I. Interview Summary

Applicants thank Examiner Helen Nguyen and Supervisory Patent Examiner Max Hindenberg for extending the courtesy of a telephone interview to Applicants' representatives on April 30, 2009. Although a final agreement could not be reached during the interview, substantial progress was made in narrowing the issues remaining in prosecution.

II. Amendments to the Claims

Applicants amend claims 1, 22, and 29 to recite that the second lumen is permanently sealed. Support for this amendment can be found throughout the specification and drawings, for example in paragraphs [0011], [0027], and [0028] and in FIG. 2.

Applicants note that to satisfy the written description requirement of § 112, an applicant must merely convey with reasonable clarity to those skilled in the art that he or she was in possession of the claimed invention at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Literal support for the claimed invention is not required to satisfy the written description requirement. *E.g., Ex parte Parks*, 30 U.S.P.Q.2D 1234, 1236 (Bd. App. 1993) ("[a]dequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention"); *MPEP* § 2163.02 ("[t]he subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement"); *MPEP* § 2173.05(i). Rather, the disclosure is sufficient if it would have conveyed to one having ordinary skill in the art that the applicant had possession of the *concept* of what is claimed. *Parks*, 30 U.S.P.Q.2D at 1236 (emphasis added). Applicant's original disclosure clearly demonstrates possession of the claimed *concept*.

In paragraph [0011], a method of manufacturing the claimed catheters is discussed in which the second lumen is filled with fluid and a solvent-based solution is sprayed over the opening formed in the sidewall of the catheter to form a flexible membrane. Applicants explain in paragraph [0027] that "the membrane 16 is effective to seal the fluid within the second lumen 14." Recognizing the

permanence of such manufacturing methods, the specification goes on to state in paragraph [0011] that "preferably, all voids in the second lumen are removed from the second lumen after the second lumen is filled with fluid, and prior to spraying the solution onto the catheter." Similarly, in paragraph [0028], Applicants reiterate that "[i]n an exemplary embodiment, the membrane 16 is spray-coated onto the catheter 10 after the lumen 14 is filled with fluid and all voids or air bubbles have been removed." Thus, prior to sealing the lumen with the sprayed-on membrane, care is taken to remove any voids or air bubbles. If anything other than a permanent seal were contemplated, this step would be unnecessary, as the lumen could always be unsealed and resealed after manufacturing the membrane to remove said voids. The specification thus makes clear that, at least in these embodiments, a permanent seal is used and therefore one having ordinary skill in the art would understand from the plain language of paragraphs [0011], [0027], and [0028] that Applicants possessed, at the time of filing, the claimed catheters having a permanently-sealed lumen.

Moreover, possession of the claimed invention can be shown using figures or diagrams. *See, e.g., Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). Figure 2 of the pending application amply demonstrates that Applicants possessed the permanently-sealed lumen recited in the claims. Figure 2 shows the claimed second lumen (14) as a solid, unbroken structure whose only openings are capped with a flexible membrane (16) and a pressure sensor (22). As explained in the specification, "the membrane 16 is effective to seal the fluid within the second lumen 14" and "the pressure sensor 22 is disposed across the open proximal end 14a of the second lumen 14 to seal the fluid within the lumen 14." *Specification* at paras. [0027] and [0030]. In other words, Figure 2 shows a lumen (14) that is fluid-sealed at both ends and along its entire length. Noticeably lacking from FIG. 2 is any coupling, port, opening, or any other element or structure that would indicate the lumen can somehow be unsealed once manufactured. Accordingly, the originally-filed disclosure conveys with reasonable clarity that Applicants possessed the permanently-sealed lumen now claimed.

Applicants also add new claims 36-44. New independent claims 36 and 43 also recite that the second lumen is permanently sealed, but are otherwise identical to independent claims 1 and 29, respectively, as previously presented on May 30, 2008 (prior to the most recent amendments thereto). Similarly, new dependent claims 37, 38, 39, 40, 41, 42, and 44 are identical to previously presented claims 14, 15, 18, 19, 20, 21, and 30, respectively. Support for these new claims is thus the same as that provided for the previously presented claims. No new matter is added.

III. Rejections Pursuant to 35 U.S.C. § 103(a) – Wallace, Goodin, Pevsner, Goldstein, and Bobo

Claims 1, 3-4, 8-10, 15, 17-18, 21-24, and 28-29 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 5,951,497 ("Wallace"), in view of U.S. Pat. No. 4,928,693 ("Goodin"), further in view of U.S. Pat. No. 4,946,464 ("Pevsner"), and even further in view of U.S. Pat. No. 5,899,937 ("Goldstein"). *Office Action* at 2. The Examiner concedes later in the Office Action, however, that this same combination of references lacks the claimed "sensor disposed across an open proximal end of the catheter" and relies on U.S. Pat. No. 5,573,007 ("Bobo") to teach this limitation. *See Office Action* at p. 11, para. 30. Accordingly, the rejection of claims 1, 3-4, 8-10, 15, 17-18, 21-24, and 28-29 over Wallace, Goodin, Pevsner, and Goldstein should be withdrawn and only the latter rejection of these same claims over Wallace, Goodin, Pevsner, Goldstein, and Bobo is addressed herein.

1. Claims 36 and 43

Although new claims 36-44 were not yet presented and thus not specifically addressed by the Examiner in the pending Office Action, arguments over the cited art for said claims are provided herein to expedite prosecution.

Independent claim 36 and 43 each recite, in relevant part, a second permanently-sealed lumen filled with an incompressible fluid and a pressure sensor disposed across an open proximal end thereof.

a. Wallace Lacks A Permanently-Sealed Lumen And Teaches Away From Permanently Sealing The Lumen

At the outset, Wallace is deficient with respect to claims 36 and 43 because it fails to teach or even suggest a sealed lumen, much less a permanently-sealed lumen as claimed. Rather, as explicitly discussed at col. 11, l. 49 of Wallace, "the proximal end 68 of the inner [pressure-sensing] tube 30 remains open" – not permanently-sealed as claimed. As shown in FIGS. 4-5 of Wallace, the proximal end (68) of the Wallace pressure-sensing lumen (30) terminates at an open connector (72). The entire purpose of the open connector (72) is to permit selective coupling to a complementary connector (98), formed on the end of a separate, reusable cable assembly (84)

that contains a pressure sensor (102). *Wallace* at FIGS. 4-5. The Wallace lumen (30), which can be opened by simply de-coupling the connectors (72, 98), is thus the exact opposite of the permanently-sealed lumen that is claimed.

In addition, no person having ordinary skill in the art would have been motivated to modify Wallace to have a permanently-sealed lumen because this would eliminate several important advantages of the Wallace device, some of which are critical to its operation. First, Wallace requires the lumen to be un-sealed in order for the device to operate. *See Wallace* at col. 12, l. 43 – col. 13, l. 47. Wallace relies on the catheter lumen being open initially at the proximal end. *See id.* This allows the male connector (72) to act as a plunger such that subsequent insertion thereof into the female connector (98) of the catheter displaces air within the female connector (98) into the balloon (42) and thereby charges the balloon with a sufficient volume of air to achieve the desired sensitivity response. *Wallace* at col. 12, ll. 48-56. By modifying Wallace to have a sealed lumen as claimed, it would be impossible to perform this critical charging step. Second, Wallace explains that separation and un-sealing of the lumen is required to "zero" the pressure sensor before each use and represents a "significant advantage over prior art systems." *Wallace* at col. 13 l. 63 – col. 14, l. 9. By disconnecting the reusable sensor assembly (84) from the catheter (10), Wallace exposes both sides of the pressure sensing diaphragm (120) to atmospheric pressure, allowing for accurate sensor "zeroing." *Id.* Modifying Wallace as suggested by the Examiner to have a permanently-sealed lumen as claimed would eliminate this advantage, as it would no longer be possible to expose both sides of the sensor to atmospheric pressure. Finally, Wallace teaches that having an unsealed lumen advantageously permits reuse of the sensor electronics with multiple patients by simply disconnecting and replacing the disposable catheter portion. *See Wallace* at col. 12, ll. 3-23 (describing interface cable assembly 84 as being reusable and including connectors, electronics, and the pressure sensor); *see generally Wallace* (referring to the assembly 84 as being "reusable" throughout). Were Wallace modified to have a sealed lumen as claimed, the expensive sensor and associated electronics would have to be disposed of along with the catheter, rather than be reused as taught.

Accordingly, Wallace lacks the claimed permanently-sealed lumen and teaches away from any modification that would require permanently sealing the lumen as claimed.

b. Modifying Wallace To Include An Incompressible Fluid Runs Counter To Its Express Teachings

The Examiner concedes that Wallace lacks a lumen filled with an incompressible fluid and relies on Goodin to remedy this deficiency, arguing that it would have been obvious to modify the gas-charged lumen of Wallace with the incompressible-fluid arrangement in Goodin to arrive at Applicants' invention.

Wallace, however, expressly teaches away from such a modification. "When the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR International Co. v. Teleflex*, 127 S. Ct. 1727, 1740 (2007) (citing *United States v. Adams*, 383 U.S. 39 (1966)).

At column 2, lines 9-63, Wallace expressly teaches away from fluid-filled devices, discussing at length the perceived "drawbacks and inherent problems" associated therewith. Wallace notes that "the performance of fluid-filled IUP devices can be problematic" due to clogging concerns and the requirement that the device be flushed and recalibrated. *Wallace* at col. 2, ll. 11-15. Wallace also explains that this can "severely compromise" the sterility of the device and interrupt the monitoring procedure. *Id.* at col. 2, ll. 15-18. Wallace goes on to disparage the refilling and recalibration steps traditionally required for fluid-filled devices, and notes that sensor-tipped devices, while generally more convenient in use than fluid-filled devices, still share the same "major disadvantage" of fluid-filled devices – "the possibility of perforating the placenta or uterus." *Id.* at col. 2, ll. 18-22, 60-63. Later in Wallace, at column 11, lines 12-38, Wallace recognizes that fluid may still undesirably be present in the lumen of gas-charged devices and teaches a way of removing it – a nylon moisture-collecting element (56). Wallace thus contains extensive teachings away from using fluid-filled devices and even takes active steps to ensure that all fluid is removed from the lumen such that only gas is present. In addition, as explained above, Wallace teaches away from sealing the lumen, which would be required in order to modify Wallace to use an incompressible fluid as claimed.

c. Wallace Lacks A Pressure Sensor Disposed Across The Open Proximal End Of The Catheter

Wallace is also deficient with respect to claims 36 and 43 because it fails to teach or suggest the claimed "pressure sensor disposed across an open proximal end of the catheter." To the contrary, as noted above, the proximal end (68) of the Wallace lumen (30) is separated from the pressure sensing diaphragm (102) by a series of connectors (72, 98). *Wallace* at FIGS. 4-5. In fact, the Wallace pressure sensor (102) is housed in a reusable cable assembly (84) that is entirely separate from the housing (18) in which the catheter lumen (30) terminates. *Id.* Wallace thus lacks the claimed pressure sensor disposed across an open proximal end of the catheter.

Conceding this deficiency, the Examiner argues that it would have been obvious to modify Wallace in view of Bobo to obtain the claimed sensor arrangement. *Office Action* at 11. Bobo however, is configured almost exactly like Wallace and therefore is merely cumulative thereof. As shown in Figures 1 and 8 of Bobo, the proximal end of the catheter is located in a proximal connector (38) while the pressure sensor (152) is located in an entirely separate connector housing (14). Bobo and Wallace are thus equally deficient in that neither reference teaches the claimed pressure sensor disposed across an open proximal end of a catheter.

2. Claims 1, 22, and 29

The Examiner argues that Wallace discloses the inventions of independent claims 1, 22, and 29, except for (1) a lumen filled with an incompressible fluid, (2) a flexible membrane that is spray-coated across an opening in the catheter, (3) a pressure sensor disposed across an open proximal end of the catheter, and (4) a membrane having a compliance that is in the range of about 0.05 μL/mmHg to 2 μL/mmHg. The Examiner relies on Goodin, Pevsner, Bobo, and Goldstein to teach these limitations, respectively, arguing that it would have been obvious to combine these five references to arrive at the claimed devices and methods. Applicants respectfully disagree.

At the outset, for the same reasons discussed above with respect to claims 36 and 43, Wallace cannot be modified in view of Goodin to have a lumen filled with an incompressible fluid, and in view of Bobo to have a pressure sensor disposed across an open proximal end of the

catheter. As discussed below, Wallace further cannot be modified in view of Pevsner to have a membrane spray-coated across an opening in the catheter or in view of Goldstein to have a flexible membrane with a compliance in the range of about 0.05 μL/mmHg to 2 μl/mmHg.

a. It Is Not Possible To Modify Wallace To Include The Spray-Coated Membrane Of Pevsner

As acknowledged by the Examiner, Wallace also fails to teach the claimed membrane that is spray-coated across an opening formed in the catheter. The Examiner relies on Pevsner to remedy this deficiency. The Pevsner spray-coating method teaches first spraying the balloon composition onto a mold or "mandril" and then removing the cured balloon from the mold. *Pevsner* at col. 3, ll. 36-39; col. 6, ll. 29-32. The claims, however, recite spray-coating across an opening in the catheter, not simply using a balloon manufactured using spray coating. In other words, the claims require that the coating be sprayed onto the catheter itself, not sprayed onto a mold first and then assembled to the catheter at some point later on once the coating has cured, as taught by Pevsner. Accordingly, Pevsner fails to remedy the deficiency in Wallace with respect to the claimed membrane spray-coated across an opening formed in the catheter. Even if Pevsner taught spray-coating directly onto the catheter as claimed, it would not be possible to modify Wallace to use such a spray-coated membrane. As shown in FIG. 16 of Wallace, the balloon (342) extends well beyond either side of the opening in the lumen (330) and is able to inflate along its entire length. As detailed in Applicants' last response, such a structure cannot possibly be formed by spray-coating directly onto the catheter as claimed because to do so would result in the balloon being substantially flush with and adhered to the outer wall of the catheter. The balloon would thus only be able to flex or inflate at the actual location of the opening into the catheter (310). Such a configuration is simply unacceptable in Wallace, where "the flaccidity of the partially-filled working volume of the balloon [3]42 will prevent the occurrence of aberrant effects in pressure detection due to temperature changes..., ... signal artifacts due to the balloon wall internal forces, or external balloon compression from debris." *Wallace* at col. 13, ll. 41-46. In other words, with the relatively taught, sprayed-on balloon that would result by combining Wallace and Pevsner, the flaccidity that is essential to proper and accurate function of Wallace would be eliminated, rendering the device unsatisfactory for its intended purpose and changing its principle of operation, in violation of MPEP § 2143.01(V) and (VI).

b. Achieving The Compliance Numbers Of Goldstein Is Not An Obvious Modification Of Wallace

Claims 1, 27, and 29 each require a flexible membrane that has a compliance in the range of about 0.05 μL/mmHg to 2 μL/mmHg. There is no teaching in Wallace of a membrane having a compliance within this range, and Wallace does not specify the compliance of the balloon (342) relied upon by the Examiner to form the claimed membrane. *See Wallace* at FIG. 16. Instead, the Examiner argues that Goldstein teaches a membrane having a compliance of 8 μL/mmHg and that, although this is four times greater than the claimed compliance range, it would have been obvious to modify the Wallace balloon to have the compliance of Goldstein.

In order to achieve an 8 μL/mmHg membrane compliance, Goldstein pressurizes a sealed chamber on one side of the membrane with compressed air. *Goldstein* at FIG. 3; col. 10. ll. 33-38. By increasing the air pressure in the chamber, the compliance of the membrane is reduced, and vice versa. *Id.* The Examiner has failed to offer any teaching or explanation as to how the balloon (362) of Wallace could somehow be modified to have a pressurized air chamber on one side thereof to achieve the compliance of Goldstein. Moreover, even if such a modification were possible, the claims require an incompressible fluid – the exact opposite of the pressurized air that is essential to Goldstein.

Moreover, when evaluating compliance values, the surface area of the membrane is essential to making any sort of quantitative comparison. *See Specification* at para. [0027] ("[t]he compliance of the membrane 16 can be altered by adjusting parameters such as the... size of the membrane 16"). The Goldstein compliance value of 8 μL/mmHg is attained with a membrane that extends across a relatively massive 900cm^3 container, and thus must necessarily have a surface area far greater than that of the Wallace balloon, which is implanted in a patient and is disclosed as being inflated to a volume of only 0.1cm^3. *See Goldstein* at col. 10, ll. 33-38; *Wallace* at col. 13, ll. 35-39. The same membrane that deflects by a volume of 8uL under one mmHg of pressure in Goldstein would not deflect by nearly that much volume if reduced to 1/100th of its size in order to fit on the Wallace catheter.[1] There is thus no teaching in any of the

[1] Assuming for example that the 900cm^3 Goldstein container is cylindrical and has a height equal to its diameter, it will have a cross-sectional surface area (and thus membrane surface area) of approximately 86cm^2. Assuming that the 0.1cm^3 Wallace balloon is cylindrical and has a height equal to its diameter, it will have an

references as to how Wallace could be modified to have the claimed compliance, much less how one could do so using a spray coating over a small intra-cranial catheter as claimed.

c. Goldstein Is Non-Analogous Art

Lastly, it is inappropriate to rely on Goldstein at all, as it is non-analogous art. To be analogous, a reference must either be within the field of the inventor's endeavor or be reasonably pertinent to the particular problem with which the inventor was involved. *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986). First, the Goldstein membrane relied upon by the Examiner is part of a resistance unit designed to simulate the peripheral fluid resistance of a human circulatory system in an apparatus for studying heart valves in a laboratory. *Goldstein* at col. 9, l. 46 – col. 10, l. 47. Such a device is clearly outside the field of the inventor's endeavor – providing a pressure sensitive membrane on an intra-cranial catheter. The fact that Goldstein and the present invention each happen to include a flexible membrane in some capacity or another does not render Goldstein analogous. Second, Goldstein is not reasonably pertinent to the particular problem with which Applicants were involved. A reference is reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). In developing the claimed compliance figures, Applicants were concerned with the problem of obtaining accurate pressure readings with the use of a relatively small implantable catheter, a sprayed-on membrane, and an incompressible fluid. *See Specification* at para. 27. The purpose of Goldstein on the other hand is to simulate human circulatory resistance in a laboratory system where size is of no concern and compliance can easily be adjusted with compressed air on one side of the membrane. *Goldstein* at col. 9, l. 46 – col. 10, l. 47. Goldstein does not use a sprayed on membrane or incompressible fluid and thus the problems and considerations associated therewith are not contemplated in Goldstein at all. Rather, Goldstein is directed to an entirely different matter than that of the claimed invention, and accordingly no inventor would have been motivated to consider Goldstein because it is simply not relevant to solving the purpose of the claimed invention. Accordingly, Goldstein is non-analogous art and

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external surface area (and thus membrane surface area) of approximately 1.2cm^2. While other configurations are certainly possible for the container and/or balloon, every practicable configuration will result in membrane surface areas that differ by orders of magnitude.

reliance thereon is inappropriate.

In sum, Wallace is deficient with respect to at least four limitations of claims 1, 22, and 29, none of which is adequately addressed by the secondary references cited by the Examiner. Moreover, Goldstein is non-analogous art, and as such cannot be relied upon to reject the claimed invention as obvious. Accordingly, claims 1, 22, 29, 36, and 43 are not obvious and represent allowable subject matter. Dependent claims 3-4, 8-10, 15, 17-18, 21, 23-24, 28, 37-42, and 44 are likewise allowable at least because they depend from allowable base claims.

IV. Dependent Claim Rejections

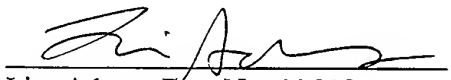
Dependent claims 11-14, 19-20, 26-27, and 32-33 are rejected over the aforementioned references in view of various additional secondary references. Each of these additional references is merely relied on to teach discrete features recited in the dependent claims, and none of these references remedy the deficiencies discussed above with respect to the independent claims. Claims 11-14, 19-20, 26-27, and 32-33 are therefore not obvious and allowable at least because they depend from allowable base claims.

V. Conclusion

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicants' amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

Date: May 29, 2009



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